UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,950	03/27/2001	Paul M. Guyre	DC-0153	4097

26259 7590 10/01/2003

LICATLA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	4

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/817,950	GUYRE ET AL.	
	Examiner	Art Unit	
	Michail A Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 7/23/03 (Paper No. 20), is acknowledged.

Claims 1-3 are pending.

Claims 1-3 are under consideration in the instant application.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/23/03 has been entered.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Coligan et al. (Current Protocols in Immunology, Greene Publishing Associates and Wiley-Interscience, New York, 1991; pages 2.1.1-2.1.3, 2.1.9-2.1.11, and 2.1.17-2.1.22) in view of U.S. Patent 5,077,216, and Zwadlo et al (IDS Reference BA) for the same reasons set forth in the previous Office Actions, Paper Nos : 9, 13 and 15 mailed on 0 8/13/02 , 03/24/03 and 7/3/03.

Applicant's arguments filed 07/23/03 have been fully considered but they are not persuasive.

Applicant asserts that : (i) the primary reference of Coligan et al teaches nothing of the temporal or spatial expression of CD163; (ii) '216 Patent does not teach temporal regulation of CD163, rather this reference teaches cell type-specific expression of 155; (iii) Zwaldo et al. teach that CD163 is a surface antigen which is expressed late in the inflammatory response ; (iv) none of the references when combined teach that CD163 is useful for monitoring an early signaling event in an inflammatory response; (iv) it is not until March 28, 2000 that the art provided the skilled artisan with the knowledge that p155 and CD163 were one and the same protein.

Contrary to Applicant's assertions, it is noted that Applicants have traversed the primary and the secondary references pointing to the differences between the claims and the disclosure in each reference. Applicant is respectfully reminded that the rejection is under 35 USC 103 and that unobviousness cannot be established by attacking the references individually when the rejection is based on the combination of the references. see In re Keller, 642 F.2d 4B, 208 USPQ 871, 882 (CCPA 1981) See MPEP 2145. This applicant has not done, but rather argues the references individually and not their combination. One cannot show non-obviousness by attacking references individually where the rejections are based on a combination of references. In re Young 403 F.2d 759, 150 USPQ 725 (CCPA 1968).

In addition, it is noted that the instant claims are drawn to a method for monitoring an inflammatory response cascade in a patient by detecting CD163. There is no recitation in the claims that CD163 is useful for monitoring an early signaling event. Moreover, Applicant himself acknowledge that Zwaldo et al. teaches the use of CD163 in monitoring late inflammatory response (see Applicant response, filed 07/23/03, page 3 in particular). It appears that applicant and the examiner differ on interpretation of both the claimed methods and the prior art. It is the Examiner's position that Zwaldo et al. teach a method of monitoring the course of an inflammatory condition/process comprising detecting RM3/1 antigen (.i.e. CD161 antigen) in biological sample. Zwaldo et al. teach that RM3/1 antigen was found to be expressed to varying degrees, depending on the stage of inflammation (see page 299 in particular). Further, in acute inflammatory sites RM3/1 positive macrophages are found in various amounts depending on the stage of inflammation (page 303 in particular). Moreover, '216 Patent teaches that expression of p155 is stimulated by inflammatory cytokines and that such response provides the means for determining or monitoring the levels of such cytokines (see column 3, lines 60-65 in particular). It would have been obvious to one of ordinary skill in the art that p155 (or CD163) is useful for monitoring inflammatory response.

With regard to Applicant comments that it is not until March 28, 2000 that the art provided the skilled artisan with the knowledge that p155 and CD163 were one and the same protein. Applicant attention is respectively drawn to ABCAM catalog, that teaches that anti-CD163 antibody reacts with CD163 that is also p155 and that this product has been used in 1988 by Morganelli et al. In addition, Applicant himself acknowledge, that monoclonal MAC2-48 antibodies that specific for CD163 were commercially available at the time the invention was made from Maine Biotechnology (see Applicant Response paper 8, page 5). The same antibodies were used in '216 Patent to detect p155. It would have been obvious to one of ordinary skill in the art at the time the invention was made that p155 and CD163 were one and

the same protein. Moreover, mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the MAC2-158 or MAC2-48 antibodies as capture antibodies taught by the '216 patent and the antibodies taught by Zwaldo et al. as the detection antibody in the ELISA assay taught by Coligan et al. to have a method for monitoring the course of an inflammatory condition or inflammatory response in a patient by detecting the levels of CD163 in the biological sample as taught by Zwaldo.

One of ordinary skill in the art would have been motivated to use the antibodies taught by the '216 patent and Zwaldo et al. in the ELISA taught by Coligan et al. because to detect and monitor the presence of CD163 in a biological sample, such as human plasma, during an inflammatory condition/process, such as rheumatoid arthritis by detecting CD163 (i.e. RM3/1 antigen) as taught by Zwaldo et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because detecting CD163 levels can be used to monitor an inflammatory response cascade in the patient, as taught by Zwaldo et al . CD163 levels in biological sample can be detected using the antibodies taught by the '216 patent and Zwaldo et al. in the ELISA taught by Coligan et al.

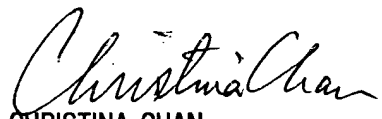
From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

5. No claims are allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskyi, Ph.D.
Patent Examiner
Technology Center 1600
September 29, 2003



CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600